

### REMARKS

Claims 1-43 constitute the claims pending in the current application. The Examiner has withdrawn claims 1-29 (in part) and 30 as being drawn to a non-elected invention. New claims 31-43 have been added. Support for these additional claims can be found at least on pp. 9, 11, 66-67, and 70-72. Issues raised by the Examiner are addressed below in the order they appear in the prior Office Action. Applicants respectfully request reconsideration in view of the following remarks.

The Examiner has withdrawn claim 30 as being directed to a nonelected species. Applicants submit that claim 30 was not directed to the compound of the structure presented in claim 30, but rather to a compound that inhibits activation of the *hedgehog* pathway by a *hedgehog* protein, but does not inhibit activation of the *hedgehog* pathway by the compound of the presented structure. The elected species falls within the scope of this claim, and thus this claim should not have been withdrawn. Furthermore, Applicants have amended claim 30 to recite a method of treatment. Support for this amendment can be found at least on pp. 11-12. Applicants respectfully traverse the withdrawal of claim 30 by the Examiner to the claim as originally filed and to the extent it is maintained over the amended claims. Applicants request reconsideration and withdrawal of the objection.

### ***35 U.S.C. § 103***

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Padia, U.S. Pat. No. 5,869,665 (hereinafter referred to as Padia). Applicants respectfully traverse the rejection to the extent it is maintained over the amended claims.

Applicants have amended the claims to recite methods of “inhibiting the *hedgehog* pathway in a normal cell, comprising administering a therapeutically effective amount of a compound which does not inhibit the *hedgehog* pathway in a *patched*-null cell.” Applicants assert that Padia does not teach or suggest that the taught compounds may be used to inhibit the *hedgehog* pathway in a normal cell and not inhibit the *hedgehog* pathway in a *patched*-null cell. Padia lists a number of uses for the taught compounds on col. 6, line 36 to col. 7, line 15 and throughout the patent, including appetite suppression, reduction of gastric acid secretion, and

anxiety reduction. However, there is no mention or suggestion that taught compounds have any effect on the *hedgehog* pathway of a normal or mutated cell. Padia did not teach, suggest, or motivation one skilled in the art to use the taught compounds for inhibiting the *hedgehog* pathway in a normal cell. As such, one of ordinary skill in the art, having read Padia, would not have predicted that the taught compounds have an effect on the *hedgehog* pathway, and would not have been motivated to use them for this purpose.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

### ***Double Patenting***

Claims 1-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-32, 34-41 and 53-59 of copending Application No. 09/687,800.

Applicants have amended the claims to recite methods for inhibiting the *hedgehog* pathway in a normal cell by administering certain compounds. Claims 31-32, 34-41, and 53-59 of copending Application No. 09/687,800 are directed to pharmaceutical preparations, compositions, or compounds. Applicants respectfully remind the Examiner of the Office Action, drafted by the Examiner and mailed December 19, 2002, requiring restriction in the parent application, Application No. 09/663,835, of the present application. In that Office Action, the Examiner required the Applicants to choose between claims directed to, among others, (1) compounds, (2) pharmaceutical compositions, and (3) methods of using said compounds, each group of claims drawn to a distinct invention. In light of the designation of the presently claimed methods as an invention distinct from the compounds and compositions claimed in other related applications, Applicants submit that an obviousness-type double patenting rejection of the present method claims over compositions and compounds is improper. Therefore, Applicants submit that the claims of Application No. 09/687,800 and the claims of the present application are patentably distinct. Applicants respectfully traverse the rejection to the extent it is maintained over the amended claims and request withdrawal of the rejection.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: February 24, 2003

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Respectfully Submitted,



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